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10/576,618

04/21/2006

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EXAMINER

HOBBS, MICHAEL L

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,618	Applicant(s) SCHULZ ET AL.	
	Examiner MICHAEL HOBBS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-119 is/are pending in the application.
- 4a) Of the above claim(s) 58-69, 72, 73, 81-84, 88-93, 96, 113 and 114 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 70, 71, 74-80, 85-87, 94, 95, 97-112 and 115-119 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/21/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species I and III in the reply filed on 11/07/2008 is acknowledged. Claims 58-69, 72, 73, 81-84, 88-93, 96 and claims 113 and 114 are withdrawn from consideration and claims 70, 71, 74-80, 85-87, 94, 97-112 and 115-119 are pending further actions upon the merits.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: in line 3 of claim 75, the limitation of "at least one conical nipple" lacks antecedent basis within the claims. In line 2 of claim 76, the term "measuring heads" lacks antecedent basis in the specification. In line 3 of claim 98, applicant refers to the "magnetic north pole" of the mini actuator which lacks antecedent basis and in lines 2-3 of claim 99 the "external form" lacks antecedent basis and is being interpreted as the external magnet. Finally, in claim 109 lines 3-4 the limitation of

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the “rectangular shaped magnet holder and moved to their horizontal position” does not appear in the specification and the terminology therefore lacks antecedent basis.

4. Appropriate corrective action is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 70, 71 and 86 are rejected under 35 U.S.C. 102(b) as being anticipated by Adamietz et al. (DE 19808055 A1) (will be referred to as Adamietz).

7. For claim 70, Adamietz discloses a bioreactor for the production of three-dimensional cell cultures that includes a reactor (Fig. 5-reactor(1)) or basic bioreactor body with a cover (Fig. 5-cover(3)) or reactor lock which defines a reactor chamber that is fully capable of being pressure-proof and sterile. Adamietz further includes a plunger (Fig. 5-plunger(6)) or mini-actuator that is within the chamber and includes connections for the culture medium to be pumped to the reactor (Fig. 2; translation page 2 paragraph 4 lines 1-3; paragraph 11 lines 1-4).

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8. For claim 71, the chamber disclosed by Adamietz is fully capable of capable of holding cell constructs and cultivating the cells on the floor of the chamber (see MPEP 2115). For claim claim 86, Adamietz discloses that a fleece can be disposed above the reactor floor (translation; page 1 paragraph 3).

9. Therefore, Adamietz meets the limitations of claims 70, 71 and 86.

10. Claims 70, 71, 74, 85, 95 and 119 are rejected under 35 U.S.C. 102(e) as being anticipated by Takagi et al. (US 2004/0235150 A1) (will be referred to as '150).

11. ('150) discloses a cell as structure incubator that for claim 70 includes a culture unit (unit 4) or bioreactor where the inner culture chamber is covered and defined by a chamber cover (cover 20) or reactor lock and the culture unit ([0039]). Within the chamber is a circular disc (disc 20) or mini-actuator that provides the force/shear necessary to cultivate the three-dimensional cells. Finally, ('150) discloses two ports (ports 12 & 14) or hose couplings that are used to deliver and remove culture medium from the chamber ([0038]).

12. For claim 71, the chamber is a single chamber and the cells are "stimulated" on the floor of the bioreactor (Fig. 1) and for claim 74, the bioreactor has a circular or cylindrical shape (Fig. 14). With regards to claim 85, the wall (wall 128) or bottom of the reactor is transparent to allow optical observation by a CCD camera (camera 130; [0075]). For claim 95, the disc or mini actuator is situated above the matrix (Fig. 1). Finally, for claim 119, the bioreactor of ('150) includes "three fixation walls" which are fully capable of not impairing a pressure compression of the transplant (Fig. 17).

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13. Therefore, ('150) meets the limitations of claims 70, 71, 74, 85, 95 and 119.

14. Claims 70, 115, 117 and 118 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson et al. (US 6,121,042).

15. Peterson discloses for claim 1 a bioreactor that includes bioreactor body (body 10) with a reactor lock or lid as being inherently part of the bioreactor. Also, Peterson discloses that the bioreactor has a treatment chamber (chamber 110), a piston (piston 112) or mini-actuator (Fig. 5a) and a membrane support as shown in Fig. 5a. Finally, Peterson discloses two hose couplings or ports (ports 132 & 134) for the perfusion of culture media through the bioreactor (col. 9 lines 44-49; col. 10 lines 21-22).

16. With regards to claim 115, the pistons of Peterson are used for seeding the bioreactor and have an outside diameter that is similar to the diameter of the transplant (Fig. 5a) and for claims 117 and 118, the piston matches the inside diameter of the bioreactor (Fig. 5a).

17. Claims 70, 71, 75, 86, 87 and 94 are rejected under 35 U.S.C. 102(b) as being anticipated by Bader (WO 2003/060055) (where US 2005/0084954 A1 is the closest English translation).

18. Bader discloses a device for cultivating cells that includes for claim 7 a receptacle (receptacle 1) or bioreactor body that comprises the receptacle, a lid (lid 3) and a lower lid (lid 12) or bottom (Fig. 13). Culture medium is delivered to the receptacle by inlet and outlet bores (bores 8 & 9) or hose connectors and force is

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applied to the cells within the receptacle by means of a magnetized pressure disk or piston (piston 25; [0045]; [0068]).

19. With regards to claim 71, the cells are stimulated on the floor of the bioreactor as shown in Fig. 13. For claim 75, Bader discloses that the receptacle and lid are threaded (threads 2 & 4) where the threads on the receptacle are being interpreted as "female threads" and the threads on the lid are being interpreted as "male threads" where the threads are fully capable of working together to seal the reactor. Also, the receptacle is being interpreted as a conical shape (Fig. 13).

20. With regards to claims 86 and 87, the mesh on the magnetic disk is being interpreted as being inert and since it allows for culture medium to pass through the disk, the mesh is being interpreted as wide-meshed, light and fluid and gas permeable (Fig. 13b; [0071]).

21. With regards to claim 94, Bader discloses controlling the magnetic disk or piston with a magnetic coil which is being interpreted as being external to the interior of the receptacle. ([0068]; Fig. 13).

22. Therefore, Bader meets the limitations of claims 70, 71, 75, 86, 87 and 94.

23. Claims 70, 71 and 94 are rejected under 35 U.S.C. 102(e) as being anticipated by Takagi et al. (US 2005/016716 A1) will be referred to as '716).

24. For claim 70, ('716) discloses an apparatus for culturing cells that includes a disk shaped chamber body (body 2) or basic bioreactor body with a reactor lock (bolts 26) which is fully capable of maintaining the interior in a sterile ([0026]). The chamber body

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(body 2) serves a matrix support and the pressing plate (plate 10) is the mini actuator within the chamber ([0029]). Finally, ('716) discloses two fluid ports (ports 36 & 38) or hose connections that are used for circulating the culture fluid ([0031]).

25. With regards to claim 71, ('716) discloses a single bioreactor chamber that cultivates a culture on the floor of the bioreactor (Fig. 9).

26. With regards to claim 94, ('716) discloses that the pressing plate is moved by an external electromagnet where the plate is being interpreted as a "piston-type actuator" ([0030]).

27. Therefore, ('716) meets the limitations of claims 70, 71 and 94.

Claim Rejections - 35 USC § 103

28. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

29. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

30. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

31. Claims 97-100, 102 and 104-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Bader (WO 2003/060055) (where US 2005/0084954 A1 is the closest English translation) in view of Spaulding (US 6,001,643).

32. Bader discloses a magnetic disc, but is silent regarding a magnetic core encapsulated in a biologically inert enveloping body.

33. Spaulding discloses a roller bottle used for culturing three-dimensional cells that for claim 97 includes a control rod (rod 11) or piston that includes a magnet (magnet 10) embedded within the control rod where the control rod is constructed of a polymer suitable for tissue culturing (col. 14 lines 2-4). The rod engages the tissue culture once the electro-magnet is energized providing a force to the cells in order to simulate *in vivo* conditions for the tissue culture. Therefore, it would have been obvious to one of ordinary skill in the art to employ the encapsulated magnet as suggested by Spaulding in order to provide a compressive force to the cells of Bader with a reasonable expectation of success.

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34. With regards to claim 98, Spaulding discloses that the poles in the magnet are oriented such that the south pole would be in the "upward" direction. However, the orientation of the poles is strictly a design choice, without unexpected results, is within the skills of one of ordinary skill in the art. Therefore, it would be obvious to one of ordinary skill in the art to employ the magnet as suggested by Spaulding in order to control the piston of Bader. See also MPEP 2144.04 VI (C).

35. For claim 99, the magnet of Bader includes an external form or cap that matches the form of the receptacle (Fig. 13) and for claim 100 the actuator results in a "vertically-oriented guiding" of the disk (Fig. 13).

36. For claim 101, Bader and Spaulding are silent regarding a bridge between the actuator and disc. However, it would be an obvious modification to one of ordinary skill in the art to include a connector or bridge between the magnet and disk of Bader and Spaulding in order to allow the disk to respond to the change in the electric field and reduce any lag time in response to movement from the magnet.

37. For claim 102, the disk of Bader runs vertical to the guide direction of the receptacle (Fig. 13) and for claim 104 Bader discloses a mesh or grid on the bottom of the disk (Fig. 13a-b). Regarding claim 105, Bader discloses flow channels (channels 26) in the disk that are fully capable of guaranteeing the vertical guiding of the disk or actuator (Fig. 13a).

38. For claim 103, the mesh surface of Bader is being interpreted as an organotypical negative surface since the cells are not meant to attach to the surface of

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the disk and the disk is being interpreted as not resembling an organ *in vivo*, thus being an organotypical negative surface.

39. For claim 106, Bader and Spaulding are silent regarding a bridge between the actuator and disc. However, it would be an obvious modification to one of ordinary skill in the art to include a connector or bridge between the magnet and disk of Bader and Spaulding in order to allow the disk to respond to the change in the electric field and reduce any lag time in response to movement from the magnet.

40. Regarding claim 107, Bader discloses an electromagnet (magnet 24) that is exterior of the disk, but is silent regarding the pole orientation of the disc. For claim 107, Spaulding discloses that the poles in the magnet are oriented such that the south pole would be in the “upward” direction. However, the orientation of the poles is strictly a design choice, without unexpected results, is within the skills of one of ordinary skill in the art. Therefore, it would be obvious to one of ordinary skill in the art to employ the magnet as suggested by Spaulding in order to control the piston of Bader. See also MPEP 2144.04 VI (C)

41. For claim 108, Bader discloses a magnet above the disc where the magnet is fully capable of being moved in order to move the magnetized disc (Fig. 12).

42. Claim 116 is rejected under 35 U.S.C. 103(a) as being unpatentable over by Peterson et al. (US 6,121,042) in view of Bader (WO 2003/060055) (where US 2005/0084954 A1 is the closest English translation).

43. Peterson is silent regarding a inert membrane over the piston.

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44. Bader discloses a mesh or membrane on the magnetic disk is being interpreted as being inert and since it allows for culture medium to pass through the disk, the mesh is being interpreted as wide-meshed, light and fluid and gas permeable (Fig. 13b; [0071]). This mesh prevents the interaction of the piston with the cells and provides a surface for the cells to attach to. Therefore, it would have been obvious to one of ordinary skill in the art to employ the mesh suggested by Bader in order to cover the piston of Peterson with predictable results.

45. Claims 76 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Bader (WO 2003/060055) (where US 2005/0084954 A1 is the closest English translation) in view of Freedman et al. (US 5,501,971).

46. Bader is silent regarding a measuring head on the cover of the reactor.

47. Freedman discloses a bioreactor for cultivating anchorage dependent cells that includes an inlet and an outlet for the supply and removal of culture medium. For claim 76, Freedman discloses a head plate (plate 36) or measuring head that is used to measure dissolved oxygen within the reactor (col. 3 lines 65-66). Typically, the inclusion of the sensor is used to allow a controller/operator to monitor the process and make additions of culture medium or removal of the cells based on the data sent from the sensor. Also, this sensor could be placed on the side or bottom of the reactor to obtain data regarding the culture medium at different places within the reactor.

Therefore, following rationale E of KSR 550 US ___, 82 USPW2d 1385 (2007), it would

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have been obvious to one of ordinary skill in the art to employ the sensor as suggested by Freedman within the receptacle of Bader with predictable results.

48. For claim 77, Bader is silent regarding a sample taking section at the top of the reactor. Freedman discloses a inlet tube (tube 30) that is closed by a plug (plug 28) that is fully capable of functioning as a sample tacking section (fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art to employ the tube of Freedman within the reactor of Bader in order to sample the top of the bioreactor with predictable results.

49. Claims 78-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Bader (WO 2003/060055) (where US 2005/0084954 A1 is the closest English translation) in view of Altman et al. (US 2004/0219659 A1).

50. Bader is silent regarding at least two feed and discharge outlets.

51. Altman discloses a multi-dimensional strain bioreactor for cultivating bioengineered tissue that for claim 78 includes multiple inlets and outlet ports (Fig. 1) that provide and remove the culture medium to the tissue sample (Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art to employ the inlets and outlets of Altman with the bioreactor of Bader with a reasonable expectation of success.

52. For claim 79, Altman discloses a three way valve that directs the culture media to either the perfusion inlet or the sheath inlet (Fig. 1). Furthermore, the valve of Altman also functions as a three-way valve for the discharge from the bottom of the reactor (see Fig. 1). Therefore, it would be obvious to one of ordinary skill in the art to employ the

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“three-way” valve as suggested by Altman in order to send the culture medium to the bioreactor of Bader. The suggestion for doing so at the time would have been in order to send the perfusate to the one or more inlets of the bioreactor ([0012]).

53. With regards to claim 80, both Bader and Altman are silent regarding a sampling port being part of the discharge section. However, it would be an obvious modification of the valves of Altman for one of ordinary skill in the art to employ a sampling port for the bioreactor of Bader.

54. Claims 109-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takagi et al. (US 2005/016716 A1) will be referred to as ‘716) in view of Takagi et al. (US 2004/0235250 A1) (will be referred to as ‘150).

55. With regards to claim 109, (‘716) does not disclose two permanent magnets above the pressing plate. However, permanent magnets are known within the art and would be one obvious to try in place of the solenoid of (‘716) for one of ordinary skill in the art.

56. With regards to claim 109, (‘150) discloses magnets (36) with a rectangular cross-sectional area that are used to rotate the interior magnets (magnets 22) of the disk. While not specifying that these magnets are permanent, the magnets of (‘150) are being interpreted as permanent magnets. Furthermore, (‘150) discloses a motor (motor 40) that is mounted and adjusted with a fixed tool (bolt guide 44) or slide that is used ‘o adjust the height of the motor ([0041]). Also, the rectangular shape of the magnet holder is a engineering design choice barring any presentation of any unexpected

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results and would be within the skills of one of ordinary skill in the art to incorporate within ('716) and ('150). With regards to the compression being controlled by a permanent magnet, there are a finite means to control the compression of the pressing plate or piston that includes an electromagnet, a permanent magnet or a pair of electromagnets to regulate the amount of force applied to the cell matrix. Therefore, it would have been obvious to one of ordinary skill in the art to employ the magnets suggested by ('150) in place of the solenoid of ('716) with a reasonable expectation of success.

57. With regards to claims 110, and 111 ('150) discloses more than one magnet and are in a disk shaped holder (Fig. 14) that can be adjusted in the vertical direction and following the reasoning used for claim 109, it would be obvious to one of ordinary skill in the art to employ circular holder as suggested by ('150) in order to apply a force to the matrix of ('250) with a reasonable expectation of success.

58. Regarding claim 112, both ('716) and ('150) are silent regarding two bioreactors. However, it would be obvious to one of ordinary skill in the art to employ more than one bioreactor in order to increase the throughput of culture material such as bone or cartilage. See MPEP 2144.04 VI (B).

Conclusion

59. Claims 70, 71, 74-80, 85-87, 94-112 and 115-119 are rejected.

60. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Vellinger et al. (US 6,312,910 B1) discloses magnetic separation

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system that uses a translation magnet that comprises a permanent dipole which is moved over the cuvette.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/M.L.H./
MICHAEL HOBBS
Examiner, Art Unit 1797

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